

# **Paradise Valley's radiology probed**

## **Mammograms continued despite orders to close**

By Cheryl Clark, STAFF WRITER, September 1, 2006

How could Paradise Valley Hospital perform mammograms on at least 6,000 women for nearly two years after being told by state officials to shut down its service and more than a year after being cited for poor quality by a national accreditation group?

That's the question federal, state and American College of Radiology officials are struggling to answer. Officials at the National City hospital also are trying to explain the situation as they send letters to physicians and patients recommending that some women undergo another mammogram to make certain breast cancers weren't missed.

"This does not necessarily mean that the results you and your health care provider were given were wrong," the letter reads. The hospital is offering a list of certified mammogram facilities in the region, and it has established a hotline to address concerns.

The mammograms in question were performed from Sept. 8, 2004, when state certification for the mammography program expired, to July 6, when state health regulators finally visited the hospital and terminated the operation.

State officials also discovered that on Aug. 3, 2005, the American College of Radiology denied accreditation for one of the hospital's mammography machines because of problems with imaging quality.

Investigations are under way by two divisions of the state Department of Health Services in Sacramento, with the involvement of federal officials.

From June to September 2004, the state sent three letters to Paradise Valley warning that certification for its mammography unit was about to lapse. But it didn't notice that the hospital continued providing mammograms until July of this year.

Asked why the state did not stop Paradise Valley's program sooner, state health spokesman Ken August said, "the facility is supposed to abide by the law. They were ordered to cease performing mammograms."

August acknowledged many gaps in California's regulatory process. In the future, he said, the state will send inspectors to verify closure the day after a program's certification has expired.

Meanwhile, radiologists for the University of California San Diego are negotiating with Paradise Valley officials to re-examine about 24,000 of the hospital's mammography images. They're also in talks to take over all of Paradise Valley's radiology operations,

including its computed tomography scanners, ultrasound equipment, X-ray machines and magnetic resonance imaging operations.

Paradise Valley officials are defending the quality of their mammograms and don't believe any women were harmed.

"We're very concerned and we understand that patients will be concerned," said Andrea Kofl, Paradise Valley's vice president of patient care services. "(But) we believe these mammograms are adequate and valid, and we even had another radiologist outside our organization" review a sampling of the images.

Kofl characterized the initial problem as one involving the failure of "paperwork that needed to go out to the state." She acknowledged that a second problem pertained to an evaluation in the summer of 2005 by the American College of Radiology, or ACR. That process, she said, "gave us recommendations that we weren't meeting some standards."

According to an Aug. 3, 2005 letter from ACR to Dr. Richard Rossin, Paradise Valley's former chief of radiology, one of the hospital's two mammography machines failed because of many problems.

The ACR evaluation faulted the hospital's staff for inadequate breast compression, incorrect breast positioning and other factors that impaired image quality.

Rossin said yesterday that he passed the ACR letter to Paradise Valley administrators, whom he described as incompetent for failing to maintain hospital equipment to meet accreditation requirements.

Rossin said he never saw the three letters from California's health regulators.

In defense of Paradise Valley, Dr. Chris Comstock, director of breast imaging for UC San Diego, said he has reviewed some of the images in question. Yesterday, he described their quality and contrast exposure as "fairly good."

Normally, Comstock said, hospitals analyze their images and select the best ones for ACR review. Perhaps untrained radiology technicians at Paradise Valley selected such images at random, he said.

"If they had come in and had taken better films, maybe they could have passed," Comstock said.

The exact sequence of events leading to the July 6 termination remained fuzzy yesterday, in part because of the interlocking authorities of state, federal and San Diego County health officials and the American College of Radiology, an organization of independent radiologists. The timing of inspections also differs for each regulatory group.

Paradise Valley underwent the state's annual site review of its mammography program in June 2004, according to Kevin Reilly, prevention services deputy director for the state Department of Health Services.

Problems were discovered with the level of training required for radiologists and technicians, and there were "moderate" problems with exposure levels on the mammogram machines, Reilly said.

The hospital took steps to correct those problems. But despite repeated requests from state officials, it did not file paperwork required for renewal of its three-year certification by Sept. 8.

In June 2005, a San Diego County health official acting on behalf of the state conducted another inspection of Paradise Valley's mammography program but did not notice the expired certification.

Paradise Valley officials said they assumed that meant the state had no problems with their program.